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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/760,144

01/15/2004

David Y. Kim

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EVAN LAW GROUP LLC

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EXAMINER

SONG, MATTHEW J

ART UNIT

PAPER NUMBER

1722

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/760,144

Applicant(s)

KIM ET AL.

Examiner

Matthew J. Song

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-8, 11-17 and 46-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8, 11-17 and 46-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 4-8, 11-17 and 46-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bray (WO 01/88231 A2 from IDS 2/14/2004) in view of Forsythe et al ("Vapor diffusion, nucleation rates and the reservoir to crystallization volume ratio" from IDS 12/14/2004).

In a method for controlling crystal growth, note entire reference, Bray et al teaches five different proteins were crystallized using either no device, or devices with 1 mm, 2mm or 3 mm diameter channels (pg 5, ln 10-35 and pg 13, ln 10 to pg 14, ln 30), this clearly suggests the effective A/L is different for the first plurality of systems because the diameter will affect the evaporation rate. This also clearly suggests applicant's concentration is substantially the same for

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the first plurality of systems because Bray teaches preparing one solution for each of the different proteins which is compared with different diameter channels (pg 13, ln 10 to pg 14, ln 30).

Bray et al clearly teaches optimizing the channel size. However, Bray does not teach the effective A/L that was different for the first plurality of systems is substantially the same, and the concentration that was substantially the same for the first plurality of systems is different for the second plurality of systems.

In a method of vapor diffusion crystallization, note entire reference, Forsythe et al teaches an experiment where lysosyme experiments that were conducted at different NaCl concentrations, 4% and 5% NaCl (pg 1603 and Table 2). Forsythe et al also teaches a third tray was set up with all ratios in duplicate wells (pg 1603). Forsythe et al also teaches greater crystal growth in the 5% NaCl solution compared to the 4% NaCl solution for the same reservoir to drop volume ratio (Table 2).

It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Bray et al by conducting experiments for different concentrations of solutions, as taught by Forsythe et al to determine the optimum solution concentration for crystal growth. Furthermore, it is known to screen more than 1000 crystallization conditions to find suitable conditions that yield high quality protein crystal, thus it would have been obvious to a person of ordinary skill in the art at the time of the invention to conduct experiments where the concentration is changed while other conditions are maintained to determine the effect of concentration on protein yield ('308 pg 2, ln 5-15).

The combination of Bray and Forsythe et al is silent to solid of a system of the second plurality comprises a crystal having a highest quality relative to the solids of the other systems of the second plurality, however this feature is expected to occur because different conditions are used thus one condition is expected to produce better results relative to the others since identical results are not expected to occur for different conditions.

Referring to claims 4-6 and 16-17, the combination of Bray and Forsythe et al is silent to the claimed variation of concentration and the claimed variation in the rate of removing solvent and the first plurality and second plurality are at least six. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the combination of Bray and Forsythe et al by using the claimed variations to obtain more experimental data to minimize the need for extrapolation for improved accuracy in the results since it is known to screen more than 1000 crystallization conditions to find suitable conditions that yield high quality protein crystal ('308 pg 2, ln 5-15).

Referring to claim 7-8, the combination of Bray and Forsythe et al hanging drop vapor diffusion crystal growth and a sitting drop crystal growth ('308 Fig 2A and Fig 2B and pg 3, ln 5-20). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the combination of Bray and Forsythe et al by carrying out the process until completion, i.e. until only solid remains.

Referring to claim 11-15, the combination of Bray and Forsythe et al teaches a protein and a material that precipitates and water (Forsythe pg 1601).

Referring to claim 47, the combination of Bray and Forsythe et al teaches experimentations with evaporation rate by controlling the diameter and changes in concentration

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on crystal growth; therefore this clearly suggests identifying the conditions that produces the most desirable result.

Referring to claim 48, the combination of Bray and Forsythe et al teaches the concentrations are the same for the first plurality.

Referring to claim 49, the combination of Bray and Forsythe et al is silent to the effective A/L is substantially the same for the first plurality. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the combination of Bray and Forsythe et al by determining the optimum concentration for a solution, as taught by Forsythe et al. Furthermore, the transposition of steps where the process are substantially identical or equivalent in terms of function, manner and result was held to be not patentably distinguish the processes. *Ex parte Rubin* 128 USPQ 159 (PO BdPatApp 1959).

Referring to claims 50-52, the combination of Bray and Forsythe et al teaches a tray that comprises a plurality of wells ('308 Fig 3 and 4), thus it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the combination of Bray and Forsythe et al by performing the removing of solvent simultaneously to increases productivity.

Response to Arguments

3. Applicant's arguments filed 5/4/2007 have been fully considered but they are not persuasive.

Applicant's argument that the prior art does not teach removing solvent from solutions having different concentration, where solutions are in systems having substantially the same effective A/L is noted but not found persuasive. Applicant alleges that Forsythe teaches a hanging drop method, in which evaporation rate varies throughout the process, thus the effective

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A/L is different because the effective A/L is proportional to the rate of evaporation. This argument is not persuasive for several reasons. First, the claim merely requires effective A/L is the same for the second plurality of systems. The claim does not require the effective A/L be constant throughout the process as implied by applicant. Forsythe teaches duplicate wells are used (see page 1603), thus the effective A/L would be same for at least the beginning of the process, which satisfies the claimed limitation.

Second, Forsythe is relied upon to modify Bray, which is not a hanging drop process. Bray teaches a process using channels and the vapor diffusion rate can be controlled by the diameter of the channel (see page 5, lines 15-35). Although Bray teaches the channel diameter can be actively controlled, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Bray by using identical chambers to determine rate for different concentrations, as suggested by Forsythe, which teaches using different solution concentration in duplicate wells.

Finally, effective A/L is dependant on the platform/apparatus dimension and evaporation rate is merely proportional to the effective A/L. Applicant teaches different solutions are preferably placed in platforms having the same effective A/L (for example, all dimensions and geometries of all cells used are identical, and thus all samples have the same rate of evaporation as determined by the length and cross-section area of the channels) (see page 7, lines 10-25 of the specification). The effective A/L defined by applicant is merely a function of the apparatus dimensions. Applicant teaches all samples have the **same rate of evaporation as determined by the length and cross section**, but the rate of evaporation is also a function of solution concentration, which is the purpose of the experiment; to determine the optimum rate of

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evaporation. Although the rate of evaporation may vary during the process, Forsythe clearly suggests the effective A/L to be the same because Forsythe teaches identical wells and effective A/L is determined by the length and cross section of the cells.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Song whose telephone number is 571-272-1468. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJS
June 28, 2007

Matthew J Song
Examiner
Art Unit 1722



**ROBERT KUNEMUND
PRIMARY EXAMINER**